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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
SCHULER ET AL.

EXAMINER: MICHAEL G. MENDOZA
ART UNIT: 3734

APPLICATION NO: 09/731,316

FILED: DECEMBER 6, 2000

FOR: SYSTEMS AND METHODS FOR TREATING PACKAGED
POWDERS

MS: Appeal Brief- Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF

Sir:

In response to the Examiner's Answer mailed on April 28, 2009, the Applicant of the above-referenced patent application (hereinafter "Appellant") hereby maintains the appeal to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

(1) *Real Party in Interest*

The real party in interest of the present application is Novartis Pharma AG, a corporation organized under the laws of Switzerland having its principal office at Lichtstrasse 35, CH-4002, Basel, Switzerland.

(2) *Related Appeals and Interferences*

Appellant and Appellant's legal representatives are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) *Status of Claims*

Claims 1-50 and 52-63 are presently pending in the case. Claim 51 has been previously cancelled. Claims 1-18, 21, 23-29, 3-39, 43-49, 61 and 62 have been finally rejected. Claims 52-60 have been allowed. Claims 19, 20, 22, 30-36, 40-42, 50, and 63 have been objected to as dependent claims containing allowable subject matter. The appeal of the rejection of each of claims 1-18, 21, 23-29, 35-39, 43-49, 61 and 62 is hereby maintained.

(4) *Status of Amendments*

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

(5) *Grounds of Rejection to be Reviewed on Appeal*

Appellant continues to request review of the Examiner's following grounds of rejection:

Claims 1, 3-7, 11, 15, 16, 18, 21, 25-29, 38, 39, 45-49, 61 and 62, rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,740,794 to Smith et al (hereinafter "Smith et al") in view of PCT Publication WO 99/44663 to McGinn et al (hereinafter "McGinn et al").

Claims 1, 8-11, 13-15, 23, 24, 26, 27, 37, 43-45 and 61, rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al in view of U.S. Patent No. 5,694,920 to Abrams et al. (hereinafter "Abrams et al").

Claim 2, rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al and McGinn et al further in view of U.S. Patent No. 6,167,880 to Gonda et al (hereinafter "Gonda et al").

Claim 12, rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al and McGinn et al further in view of Abrams et al.

(6) Argument

Appellant believes each of claims 1-18, 21, 23-29, 35-39, 43-49, 61 and 62 are improperly rejected and are therefore allowable for the reasons set forth in the Appellant's Appeal Brief filed on October 30, 2006 and Supplemental Appeal Brief filed on September 28, 2007. The present Reply Brief is being filed to specifically address some of the issues raised by the Examiner in the Examiner's Answer mailed on April 28, 2009. The comments herein are supplemental to the arguments made in the Appeal Brief and Supplemental Appeal Brief and are not meant to replace those arguments.

Smith et al and McGinn et al, alone or in combination, do not disclose the powder conditioning device/ method of independent claims 1, 15, 46 and 61

The Examiner erroneously states that that independent claims 1, 15, 46 and 61 are unpatentable under 35 U.S.C. 103(a) in view of Smith et al and McGinn et al. On page 3 of the Examiner's Answer, the Examiner expressly admits that "Smith et al fails to teach providing at least one pulse of energy to the receptacle". The Examiner, however, fails to provide support for his assertion that McGinn et al provides any teaching or suggestion for the use of at least one pulse of energy to the receptacle to deaggregate or condition medicament for the delivery of drug to the patient.

On page 3 of the Examiner's Answer, the Examiner correctly states that McGinn et al teaches a method using a common pulse of energy "to release medicament". The Examiner does not provide any support for his assertion that one of ordinary skill in the art would obviously know to include the step of McGinn et al to "release/deaggregate" medicament for delivery to the patient as required in the presently claimed invention. (Page 3). As the United States Supreme Court articulated in *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007), "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

In determining the differences between the prior art and the claims under 35 U.S.C. 103, the fact-finder must compare the whole claimed invention with the entire prior art reference. M.P.E.P. §2141.02. The question is not whether the differences themselves would have been obviousness, but whether the claimed invention as a whole would have been obvious. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530 (Fed. Cir. 1983). Further, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. M.P.E.P. §2141.02 (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983)).

The Examiner improperly ignores the express teachings of McGinn et al in determining the alleged obviousness of the claimed invention. Contrary to the Examiner's assertion, McGinn et al does not disclose a method "to fluidizing an agglomerate by providing a mechanical pulse

to a cartridge prior to inhalation” (pages 3 and 8, Examiner’s Answer). McGinn et al expressly discloses that it minimizes forces of adhesion and agglomeration between the particle and substrate or between two particles by the using electrostatic deposition or similarly charged particles. (McGinn et al, page 16, Ins. 3-11.) In contrast, McGinn et al expressly discloses that the application of a pulse of energy may be used to effectively form a powder cloud for inhalation for drug release or “drug removal”. (McGinn et al, e.g., page 22, Ins 3-6; page 24, lines 11-20; page 32, lines 1-5.) McGinn et al. does not disclose any method/ device providing at least one pulse of energy to the receptacle for conditioning powders to increase aerosolization efficiency.

Further, the Examiner improperly ignores the contrasting teachings of Smith et al and McGinn et al in determining that one of ordinary skill would be motivated to combine these references to arrive at the claimed invention. On page 7 of the Supplemental Appeal Brief, Appellant explains in detail that Smith et al and McGinn et al disclose two different types of aerosolization mechanisms and renews these arguments. The Examiner uses impermissible hindsight and mischaracterizes the Smith et al and McGinn et al references in his determination of motivation to combine (page 8 of the Examiner’s Answer). It is unsupported and purely speculative that one of ordinary skill would be motivated to combine Smith et al and McGinn et al as asserted by the Examiner. Furthermore, McGinn et al does not provide an alternative method to Smith et al for “fluidizing an agglomerate by providing a mechanical pulse to a cartridge prior to inhalation” for the above reasons.

The Examiner incorrectly suggests that that the only difference between the invention of independent claim 46 and Smith et al in view of McGinn et al is the inclusion of general “instructions” (pages 4-5, Examiner’s Answer). This assertion is inconsistent with independent claim 46 which express require both “an aerosolization mechanism to aerosolize the powder in the receptacle by flowing gas through the chamber” and “instructions describing a method for providing at least one pulse of energy to the receptacle prior to aerosolizing the powder”. It is not inherent to include the required instructions in a kit (pages 4-5, Examiner’s Answer) since, as explained above, the teachings of Smith et al and McGinn et al cannot be combined to obtain the claimed invention.

Smith et al and McGinn et al do not teach or suggest each limitation of the claimed invention. Specifically, these references do not disclose providing a pulse of energy to the receptacle to increase aerosolization efficiency **and** flowing a gas through the chamber to aerosolize the powder. For at least these reasons and for the reasons set forth in the Appeal Brief and the Supplemental Appeal Brief, independent claims 1, 15, 46 and 61 are patentable under 35 U.S.C. 103 over Smith et al in view of McGinn et al.

Abrams et al does not cure the clear deficiencies of Smith et al

The Examiner erroneously states that that independent claims 1, 15, 37 and 61 are unpatentable under 35 U.S.C. 103(a) in view of Smith et al and Abrams et al. Contrary to the Examiner's assertion, Abrams et al does not teach "a method using a common pulse of energy to deaggregate medicament" (page 6, Examiner's Answer) in accordance with the claimed invention.

The Examiner improperly ignores the express teachings of Abrams et al in determining the alleged obviousness of the claimed invention. Abrams et al expressly discloses that it aerosolizes "deaggregated particles, which carry an electrostatic charge" by applying an electrostatic force to the particles with an electrostatic plate. (Abrams et al, e.g., col. 6, Ins. 1-24, 32-36.) Abrams et al does not teach the any method/ device providing at least one pulse of energy to the receptacle for conditioning powders to increase aerosolization efficiency **and** flowing a gas through the chamber to aerosolize the powder.

One of ordinary skill in the art at the time the invention was made would not be motivated to combine the teachings of Smith et al and Abrams et al to obtain the claimed invention. On page 8 of the Supplemental Appeal Brief, Appellant explained in detail that Smith et al and Abrams et al use two contrasting methods for aerosolizing the powder. If one of ordinary skill in the art were to modify the Smith et al device in accordance with the teachings of Abrams et al as a whole, then a vibration/ electrostatic aerosolization mechanism would be used instead of the airflow aerosolization recited in pending claims 1, 15, 37 and 61. The Examiner clearly uses impermissible hindsight to pick and choose aspects of Smith et al and Abrams et al and combine them in a manner that reads upon the Appellant's claim, absent any suggestion. When the teachings of Abrams et al as a whole are considered, the reference is not combinable in a way that renders independent claims 1, 15, 37 and 61 unpatentable.

Smith et al and Abrams et al do not teach or suggest each limitation of the claimed invention. Specifically, these references do not disclose providing a pulse of energy to the receptacle to increase aerosolization efficiency **and** flowing a gas through the chamber to aerosolize the powder. For at least these reasons and for the reasons set forth in the Appeal Brief and the Supplemental Appeal Brief, independent claims 1, 15, 37 and 61 are patentable under 35 U.S.C. 103 over Smith et al in view of Abrams et al.

Dependent claims are allowable for at least the same reasons as their base claims

Since claims 2-14, 16-36, 38-45, 47-50, 62 and 63 incorporate each limitation of the independent claims from which they depend, these dependent claims are not rendered unpatentable for at least the same reason as their base claim.

On page 3 of the Examiner's Answer, the Examiner asserts that dependent claims 38 and 39 are obvious over Smith et al in view of McGinn et al. It should be noted that the Examiner does not similarly assert that these references render obvious independent claim 37

(from which both claims 38 and 39 depend). Since they incorporate each limitation of independent claim 37, dependent claims 38 and 39 are allowable under 35 U.S.C. 103(a) over Smith et al in view of McGinn et al.

The Examiner erroneously asserts that claim 2 is unpatentable under 35 U.S.C. 103(a) over Smith et al and McGinn et al further in view of Gonda et al. Dependent claim 2 incorporates each limitation of independent claim 1 and thus not rendered unpatentable by Smith et al and McGinn et al further in view of Gonda et al. First, it has been previously explained that there is no motivation to combine Smith et al and McGinn et al. Second, Gonda et al does not cure the deficiencies of Smith et al and McGinn et al as compared to the claimed invention. Gonda et al instead uses a flexible, porous membrane protruding through the boundary layer into the faster moving air to avoid the coagulation of particles. (Gonda et al., e.g., col. 18, lns. 30-40.) Third, Gonda et al and Smith et al and McGinn et al use different methods for deaggregation and/or aerosolization. If one of ordinary skill in the art were to follow the teachings of Gonda et al as a whole in accordance with the teachings of Smith et al and McGinn et al, then a flexible, porous membrane would be used to minimize coagulated particle used instead of the pulse of energy and airflow aerosolization recited in pending claims 1 and 2. Contrary to the Examiner's assertion, Gonda et al in view of Smith et al and McGinn et al does not teach the use of a pulse of energy to the receptacle to increase aerosolization efficiency **and** flowing a gas through the chamber to aerosolize the powder.

The Examiner further erroneously asserts that claims 10, 13 and 14 are unpatentable under 35 U.S.C. 103(a) over Smith et al and Abrams et al. Applicant submits that dependent claims 10, 13 and 14 incorporate each limitation of independent claim 1 and thus not rendered unpatentable by Smith et al in view of Abrams et al for the same reasons set forth above and for the same reasons set forth in the Appeal Brief and Supplemental Appeal Brief for independent claim 1. The Examiner admits that Smith et al and Abrams et al fail to teach vibrating the transducer at a frequency of at least about 10 kHz (as required in dependent claims 10 and 13) and vibrating the receptacle for about 0.01 minute to about 10 minutes (as required in dependent claim 14). Contrary to the Examiner's assertion, dependent claims 10 and 13 do not merely differ from Smith et al and Abrams et al by the vibrating frequency level of at least about 10 kHz. Dependent claim 14 does not merely differ from Smith et al and Abrams et al by the length of time required for vibrating the receptacle. Dependent claims 10, 13 and 14 require a pulse of energy to the receptacle to increase aerosolization efficiency **and** flowing a gas through the chamber to aerosolize the powder. None of these limitations are taught or suggested by Smith et al in view of Abrams et al.

The Examiner further erroneously asserts that claim 12 is unpatentable under 35 U.S.C. 103(a) over Smith et al and McGinn et al further in view of Abrams et al. Dependent claim 12 incorporates each limitation of independent claim 1 and thus not rendered unpatentable by Smith et al and McGinn et al further in view of Abrams et al. The proposed modifications do not

make up for the deficiencies of Smith et al, McGinn et al and Abrams et al for the reasons discussed above and for the reasons discussed in the Appeal Brief and Supplemental Appeal Brief. Contrary to the Examiner's assertion, Smith et al and McGinn et al in view of Abrams et al does not teach the use of a pulse of energy to the receptacle to increase aerosolization efficiency **and** flowing a gas through the chamber to aerosolize the powder.

The Examiner further erroneously asserts that claims 48 and 62 are unpatentable over Smith et al and McGinn et al. Dependent claim 48 incorporates each limitation of independent claim 46, and dependent claim 62 incorporates each limitation of independent claim 61. Accordingly, dependent claims 48 and 62 are not rendered unpatentable by Smith et al and McGinn et al for the reasons discussed above and for the reasons discussed in the Appeal Brief and Supplemental Appeal Brief for independent claims 46 and 61.

Since independent claims 1, 15, 37, 46 and 61 are patentable for the reasons discussed above and in the Appeal Brief and Supplemental Appeal Brief, the claims depending therefrom are also allowable.

(7) Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments and the arguments provided in the Appeal Brief and Supplemental Appeal Brief. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representatives may be reached at the number listed below.

Respectfully submitted,

Novartis
Patents Pharma
One Health Plaza, Building 101
East Hanover, NJ 07936-1080
(862) 778-9949


Sandra S. Shim
Attorney for Applicant
Reg. No. 63,920

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